

## **REMARKS/ARGUMENTS**

### **I. Status of Claims**

- a. Claims 1, 3-5, 7-13, 15-17, 26 and 31 are pending in the application.
- b. Claims 1, 12, 13, 16, 26, and 31 are independent claims.
- c. Claim 31 is objected to for a typographical informality
- d. Claims 1, 3-5, 7-13, 15-17, 26 and 31 stand rejected under 35 U.S.C. 112 for having insufficient antecedent basis for a claim limitation.
- e. Claims 1, 3-5, 7-13, 15-17, 26 and 31 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- f. Claims 1, 3-5, 7-13, 15-17, 26 and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vilsmeier et al. (US 6,611,700) in view of Danisch (US 6,127,672), or non patent literature Measureand Inc.
- g. The following comments will be made with reference to the published Patent Application for this case, United States Patent Application Publication No.: US 2002/0087101 A1.

### **II. Response to Examiners "Response to Arguments"**

We thank the Examiner for indicating that Applicant's arguments filed on 4/24/08 with respect to claims 1, 3-5, 7-1 3, 15-1 7 and 31 are now considered moot.

However, Applicant feels obliged to comment on the Examiners comments related to his interpretation of the prior art in his response to our previous arguments. On page 3 of the Office Action, "The examiner interpreted the term "internal images" as data images already acquired to be related with the curvature sensor data to create a 3D model."

However, Applicant would like to point out that one cannot use "already acquired" images to be related with the curvature sensor data to create a 3D model since the already acquired images do not contain the fiducials of the curvature sensor. The interpretation proposed by the examiner would require the additional step of relating the external curvature data with the internal 3D images. In the currently claimed invention, the fiducials need to be imaged along with the internal images in order to preclude the requirement for the additional step.

### **III. Claim Objections**

Claim 31 is currently objected to because of the following informalities: In line 8, the letter "a" before "a 3-D internal image set" needs to be deleted. Accordingly, Applicant has amended Claim 31 to delete this typographical error. Therefore, withdrawal of this rejection is respectfully requested.

### **IV. First Claim Rejection under 35 USC § 112**

Claims 1, 3-5, 7-13, 15-17, 26 and 31 stand rejected under 35 U.S.C. 112. Specifically, the Examiner states that there is insufficient antecedent basis for the claim limitation "a 3-D internal image set of the patient".

Applicant would like to point out to the Examiner that paragraphs 55 and 56 of the published application provide antecedent basis for the claim limitation "a 3-D internal image set of the patient." These paragraphs, read together with the information disclosed in FIG. 7 and related item 800 in FIG. 8A, provide antecedent basis for the claim limitation "a 3-D internal image set of the patient". As disclosed in paragraphs 55 and 56, a 3-D Imaging System 710 (e.g. a CT or MRI imager) provides a volumetric image digitized data set 715 as part of an imaging study resulting in "a 3-D internal image set" containing patient, attachment fixture, and fiducials (see item 800).

For clarity's sake, copies of the two relevant paragraphs providing support for this argument are shown below:

[0055] Referring to **FIG. 7**, an IGT/IGS system comprises the functional elements of **a 3-D imaging system** 710, a computer image processing system 720, a curvature sensor system 730, an image display device 740 and a user interface 750. The **3-D imaging system** 710, which **may be a CT or MRI imager**, provides a **volumetric image digitized data set** 715

to the computer image processing system 720. The curvature sensor system 730 provides digitized information 735 on the 3-D position and orientation of the individual curvature sensors to the computer image processing system 720. The computer image processing system 720 correlates the image data set and the curvature sensor 3-D position information and provides a video output 745 to the image display device 740 that superimposes an image of the surgical instrument on the correlated volumetric image of the patient. Operator commands 755 is provided from the user interface 750 to the computer image processing system 720.

[0056] The operation and method of using an IGT/IGS embodiment of the present invention may be explained with reference to **FIG. 8A and 8B**. Prior to the operation, the patient undergoes an **imaging study (step 800)** wherein **a 3-D internal image set** is taken of the portion of the patient's body that will be operated upon. **In preparation for this imaging study, curvature sensor(s) (e.g. a curvature sensor garment), fiducials and/or an attachment fixture for the curvature sensor are applied to the patient,** such as with adhesive so their positions on the body are recorded in the same imaging study. The imaging study data set is then processed (step 805) wherein **the computer image processor locates the position of the attachment fixture with respect to the patient's anatomy,** the fiducials and, if employed, the curvature sensor garment,

and calculates their positions and orientations within the image data set.

Next, (step 810) the attachment fixture is marked on the image data set.

Therefore, because the Application, as discussed immediately above, provides antecedent basis for the claim limitation "a 3-D internal image set of the patient", withdrawal of these rejections is respectfully requested.

**V. Second Claim Rejection under 35 USC § 112**

Claims 1, 3-5, 7-1 3, 15-1 7, 26 and 31 are currently rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that it is unclear as to how the 3D internal image sets of the patient are acquired, and therefore it is unclear as to how these internal images are related to the curvature sensor.

Applicant again invites the Examiner to review the previously recited paragraphs 55 and 56 read together with the information disclosed in FIG. 7 and related item 800 in FIG. 8A. These sections of the application disclose specific examples of how the 3D internal image set of the patient is acquired (e.g. a CT or MRI imager) and how these internal images are related to the curvature sensor. As disclosed in paragraphs

55 and 56, a 3-D Imaging System 710 (e.g. a CT or MRI imager) provides a volumetric image digitized data set 715 as part of an imaging study resulting in "a 3-D internal image set" containing patient, attachment fixture, and fiducials (see item 800).

Therefore, because the Application discloses how the 3D internal image set of the patient is acquired and how these internal images are related to the curvature sensor, withdrawal of these rejections is respectfully requested.

**VI. Claim Rejections - 35 USC § 103(a)**

Claims 1, 3-5, 7-13, 15-17, and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vilsmeier et al. (US 6,611,700) in view of Danisch (US 6,127,672), or non patent literature Measureand Inc.

It appears to Applicant that these rejections are identical to rejections made in the Office Action dated Feb. 5, 2008 (and nearly identical to rejections made in the Office Action dated July 23, 2007), for which the Examiner had indicated that Applicants' arguments are now moot. Therefore, Applicant is essentially repeating the earlier argument below that was previously made in the RCE and REQUEST FOR RECONSIDERATION dated April 24, 2008 and noted in the Amendment dated Nov. 15, 2007.

Applicant realized that an important aspect of the presently disclosed invention may not have been adequately claimed. Mainly, that external curvature data be used to derive a frame of reference for a 3-D internal image set of a patient. This relationship may then be used to assist surgery or therapeutic intervention(s) on the patient." To explicitly claim this aspect of the invention, independent claims 1, 12, 13, 16, and 26 were amended to add a limitation to "... relate the curvature of the first non-invasive curvature sensor to the location of the imageable fiducials and a 3-D internal image set of the patient." (See Amendment dated Nov. 15, 2007, pg. 10, paras. 1 - 2). Applicant thanked the Examiner for stating in the Office Action dated February 5, 2008 that this amendment more accurately claims the invention.

After stating that "Vilsmeier does not explicitly teach a non-invasive curvature sensor that provides external curvature data and a 3D internal image set," the Examiner declared that "medical devices for the application of therapeutics on a patient that has a non-invasive curvature sensor that provides external curvature data and a 3D internal image set, are conventional in the art as evidenced by the teachings of Danisch (6,127,672) and non-patent literature Measurand Inc." (Office Action dated Feb. 5, 2008, Pg. 3, Para. 2). Specifically, the Examiner indicated that the Claim limitation "3D internal image set" is taught by Measurand Inc. (*See id.*).

In support of this statement, the Examiner noted that "... the non-patent literature Measurand Inc., uses a fiber optic based 3D bend and twist sensor, that knows where it is continuously along its length, providing accurate position and orientation information, even when in partial or variable contact with an object or person. It can be used on its own, built into or attached to a structure, or attached to a person to form real-time 3D computer images and collect data corresponding to complex shapes 3-D motion data images are created which later can be edited using software that relates the curvature data with 3D images to create a 3D surface." (Office Action dated Feb. 5, 2008, Pg. 2, Para. 4). However, Applicant notes that Measurand only discloses external 3D image sets, whereas, the presently claimed embodiments "... relate the curvature of the first non-invasive curvature sensor to the location of the imageable fiducials and a 3-D internal image set of the patient." (Appl., Claim 1)

Therefore, because Measurand does not disclose a "3D internal image set," withdrawal of these rejections is respectfully requested.

### ***III. Conclusion***

For all of the reasons advanced above, Applicants respectfully submit that the application is in condition for allowance and that action is



respectfully solicited. If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's agent at the telephone number shown below.

In the event that an extension of time is required, or may be required in addition to that requested in a petition for an extension for time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 503212.

Respectfully submitted,

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